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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,078	09/09/2003	Gopi M. Venkatesh	451194-092	1435

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EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,078	<b>Applicant(s)</b> VENKATESH ET AL.	
	<b>Examiner</b> Yong S. Chong	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Application***

This Office Action is in response to applicant's arguments filed on 1/19/06.

Claims 10-12 have been withdrawn. Claims 4-5 have been amended. Claims 1-14 are pending. Claims 1-9, 13-14 are examined herein. Applicant's arguments have been fully considered but found persuasive to withdraw the 112-2<sup>nd</sup> rejections on claims 4-5 only, but maintain the 112-2<sup>nd</sup> rejection for being indefinite with regard to "dissolution rate controlling polymers" as well as the 102(e) and 103(a) rejections for reasons of record.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the term "dissolution rate controlling polymer" is indefinite. Any polymer in the composition would be reasonably expected to affect the "dissolution rate." There is no clear definition in the specification as to what a "dissolution rate controlling polymer" actually is nor is there any explanation as to why the polymers recited in claim 5 are not "dissolution rate controlling polymers."

***Response to Arguments***

Applicant argues that the term "dissolution rate controlling polymer" is a term of art known to those of ordinary skill in the art. Examiner finds this not persuasive as the specification gives no guidelines or criteria as to how a polymer would or would not qualify as a "dissolution rate controlling polymer."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-9, 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Rampal et al. (WO 03/017981).

Rampal et al. teach a controlled release formulation of clarithromycin (abstract). The composition in Example 7 is comprised of clarithromycin (84.8%), hydrophilic binder and film coat (methocel - hydroxypropylmethylcellulose) (1.75%), lactose (6.36%), magnesium stearate (1.06%), talc (0.85%), and colloidal silicon dioxide (0.43%). The composition in Example 8 is comprised of clarithromycin (84.6%), hydrophilic binder and film coat (methocel - hydroxypropylmethylcellulose) (2.35%),

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lactose (4.2%), water-soluble excipient (polyvinylpyrrolidone) (2.1%), magnesium stearate (1.1%), talc (0.85%), and colloidal silicon dioxide (0.40%).

Rampel et al. also teach a method of preparation in Example 7. Clarithromycin was blended with the two polymers and lactose and granulated with a solution of methocel E50 in water. The granules were dried, sized, mixed with the remaining excipients and compressed to tablets (pg. 12, lines 10-12).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 7 is rejected under 35 U.S.C. 103(a) as being obvious over Rampal et al. (WO 03/017981) as applied to claims 1-6, 8-9, 13-14 in view of Vanderbist et al. (WO 02/24174 A2).

The instant claims are directed to an extended release tablet comprised of a macrolide antibiotic, water-soluble excipients, and a tableting aid (microcrystalline cellulose).

Rampal et al. teach as discussed above, however fails to disclose a composition comprising microcrystalline cellulose in the amount of not more than 5% by weight.

Vanderbist et al. teach a sustained release composition containing clarithromycin (abstract) with between 5 to 50% by weight of microcrystalline cellulose (pg. 13, lines 6-8).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, for Rampal et al. to add 5% of microcrystalline cellulose to the composition as disclosed by Vanderbist et al.

A person of ordinary skill in the art would have been motivated to add microcrystalline cellulose to the composition taught by Rampal et al. because according to Vanderbist et al., excipients such as microcrystalline cellulose always guarantees the optimal dissolution of clarithromycin (pg. 7, lines 24-28).

### ***Response to Arguments***

Applicant argues that Rampal et al. would not qualify as a prior art because the use of rate controlling polymers are disclosed. Again, the Examiner does not know what criteria is used to classify a "dissolution rate controlling polymer." All of the polymers in Example 7 disclosed by Rampal et al. have also been disclosed by the applicants in the composition of the instant invention as read in claims 1 and 5. Since

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applicant claims that the polymers in claims 1 and 5 are considered not to be "dissolution rate controlling polymers," the same logic applies to the compositions disclosed by Rampel et al. Examiner would like to know how or why the polymers in claims 1 and 5, for example polyvinylpyrrolidone and hydroxypropylmethylcellulose, do not affect the rate of dissolution in a composition.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

  
SHENGJUN WANG  
PRIMARY EXAMINER